510(k) Summary

MAR 2 5 2014

ADMINISTRATIVE INFORMATION

Manufacturer Name: X-spine Systems, Inc.
452 Alexandersville Rd.
Miamisburg, OH 45342

Telephone (937) 847-8400
FAX (937) 847-8410

Official Contact: David Kirschman, M.D.
Chief Medical Officer

Date Prepared: March 18, 2014

DEVICE NAME

Trade/Proprietary Name:	Silex™ Sacroiliac Joint Fusion System
Classification Name:	Smooth or threaded metallic bone fixation fastener
Regulation Description:	Sacroiliac Joint Fixation / Sacroiliac Joint Fusion
Device Class:	Class II
Product Code:	OUR
Regulation Number:	§888.3040

ESTABLISHMENT REGISTRATION NUMBER

The X-spine Systems, Inc. establishment registration number is 3005031160. The owner/operator number for X-spine Systems, Inc. is 9063903.

INDICATIONS FOR USE

The Silex Sacroiliac Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

DEVICE DESCRIPTION

The Silex Sacroiliac Joint Fusion System consists of bone screws in various diameters, lengths and thread configurations to accommodate variations in patient anatomy. The Silex system is manufactured from Titanium alloy in accordance with ASTM F136, and the larger diameter (12.5mm) implants may optionally have the exterior surfaces plasma coated with medical-grade commercially pure titanium (CP Ti) per ASTM F1580. Silex implants are intended for single use only and should not be reused under any circumstances.

The implants and associated components are provided clean and non-sterile. These devices are sterilized by a healthcare professional using a steam autoclave in accordance with the instructions for use provided by X-spine Systems Inc., as well as the instructions provided by the manufacturer of the autoclave.

The purpose of this submission is to modify the Indications for Use (IFU).

PREDICATE DEVICES

- X-spine Systems, Inc. – Silex Sacroiliac Joint Fusion System (K123702)
- SI-Bone, Inc. – iFuse Implant System (K131405)
- Zyga Technology, Inc. – SImmetry Sacroiliac Joint Fusion System (K130092)
- Globus Medical, Inc. – SI-LOK Sacroiliac Joint Fixation System (K112028)
- Medtronic Sofamor Danek, Inc. – MSB Sacroiliac Joint Fusion System (K110472)

EQUIVALENCE TO MARKETED PRODUCT

X-spine Systems, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Silex Sacroiliac Joint Fusion System is substantially equivalent to predicate devices based on a comparison including the following characteristics:

- FDA Product Code
- Indications for Use
- Surgical Approach
- Anatomical Region
- Implant Materials
- Product Dimensions

PERFORMANCE DATA

No performance testing was required to support the modification to the Indications for Use as there are no changes to the technological characteristics of the device.

In summary, the Silex Sacroiliac Joint Fusion System is substantially equivalent to predicate devices and is capable of performing in accordance with its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 25, 2014

X-Spine Systems, Incorporated
David Kirschman, M.D.
Chief Medical Officer
452 Alexandersville Road
Miamisburg, Ohio 45342

Re: K140079
Trade/Device Name: Silex™ Sacroiliac Joint Fusion System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR
Dated: February 10, 2014
Received: February 11, 2014

Dear Dr. Kirschman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K140079

Device Name
Silex Sacroiliac Joint Fusion System

Indications for Use *(Describe)*

The Silex Sacroiliac Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

PSC Publishing Services (301) 443-6740 EF